UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	**CONFIDENTIAL: FILED UNDER SEAL PURSUANT TO OMNIBUS SEALING ORDER ENTERED ON 12/3/2015** Civil Action No. 3:14-cv-07869(MAS)(LHG) Civil Action No. 3:14-cv-08082(MAS)(LHG) Civil Action No. 3:15-cv-02631(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACCORD HEALTHCARE, INC., Defendant.	Civil Action No. 3:14-cv-08079(MAS)(LHG) Civil Action No. 3:15-cv-02520(MAS)(LGH)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BPI LABS, LLC AND BELCHER PHARMACEUTICALS, LLC, Defendants.	Civil Action No. 3:14-cv-08081(MAS)(LHG) Civil Action No. 3:15-cv-02521(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. APOTEX CORP. AND APOTEX, INC., Defendants.	Civil Action No. 3:15-cv-00287(MAS)(LHG) Civil Action No. 3:15-cv-01835(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	Civil Action No. 3:15-cv-00289(MAS)(LHG) Civil Action No. 3:15-cv-01836(MAS)(LHG)
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DEFENDANTS' JOINT RESPONSIVE CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION.

Pursuant to Local Patent Rule 4.5(c) and the Court's November 11, 2015 and January 22, 2016 Orders (ECF Nos. 55 and 67) (amending the June 12, 2015 Pre-trial Scheduling Order), Defendants[1] respectfully submit this Joint Responsive Claim Construction Brief.

Defendants' proposed constructions of the disputed terms of the '907 and '592 patents rely largely upon intrinsic evidence, such as the plain language of the patents-in-suit, as well as legal precedent. Sanofi, in contrast, seeks to expand the scope of the relevant claims by advocating broad and vague definitions without an intrinsic basis, and without persuasive authority. Defendants respectfully request that the Court consider and adopt the proposed constructions proffered by Defendants.

II. ARGUMENT.

A. "Acetone Solvate" Means "A Solid Crystalline Material that Incorporates Between 5% and 8% by Weight of Acetone Molecules Within the Crystal Lattice."

The parties agree on several characteristics of the claim term "acetone solvate" featured in Defendants' construction. The parties agree that "acetone solvate" is a solid crystalline material. The parties also agree that the claims require that the acetone be incorporated into the crystal structure. ECF No. 59-8 at ¶ 40 (Sanofi's expert stating that "acetone solvate" "means a solid crystalline solvate that contains acetone solvent incorporated within the crystal lattice"); ECF No. 58 at 6. The parties agree that the term "acetone solvate"[2] should receive the same

[1] Capitalized terms in Defendants' Joint Responsive Claim Construction Brief will have the same meaning as defined in Defendants' Joint Opening Claim Construction Brief ("Opening Brief"), unless otherwise defined herein.

[2] The Joint Claim Construction and Prehearing Statement contained a typographical error in Defendants' proposed construction of the term "acetone solvate" in the '907 patent, but that Statement included the correct construction—"a solid crystalline material that incorporates *between* 5% and 8% by weight of acetone molecules within the crystal lattice"—for the '592 patent. ECF No. 51-1 at A-10. Defendants' proposed construction of "acetone solvate" in the

construction in both the '907 and '592 patents. ECF No. 59 at 10; ECF No. 58 at 4. And finally, the parties agree that the intrinsic record must be consulted to determine the range of acetone required by the claims. The parties disagree, however, with respect to: (1) the amount of acetone required to be present in the acetone solvate, and (2) whether the Court should read the phrase "and exhibiting a powder x-ray diffraction pattern consistent with that of Figure 1 of the '907 patent" into the construction, as Sanofi proposes. If Sanofi's proposed construction is adopted, the claims of the '907 patent would be so broad that they would cover *any* solvate of cabazitaxel so long as there is "about" 0.02% acetone by weight and a PXRD pattern "consistent with" Figure 1.

1. The Claimed "Acetone Solvate" of Cabazitaxel Has Between 5% and 8% Acetone By Weight.

Based upon the specification, a POSA would interpret the claimed "acetone solvate" to have between 5% and 8% acetone by weight. The only example of an acetone solvate of cabazitaxel disclosed in the specification of the '907 patent is "form A," which contains about 7.2% of acetone by weight. ECF No. 58 at 6-7. Sanofi's construction greatly expands the scope of the claims to include *any* cabazitaxel solvate that contains as little as 0.02% acetone by weight incorporated into the crystal structure. To do this, Sanofi and its expert Dr. Atwood postulate without reference to the disclosure of the patents that the acetone solvate claimed in the '907 patent is a non-stoichiometric "channel" solvate from which the acetone may be removed without alteration of the physical crystal structure. ECF No. 59 at 7; ECF No. 59-8 at ¶¶ 44-46. Sanofi then relies on the "Drying Study," described in the '907 patent (but not mentioned in the '592 patent), and concludes that a cabazitaxel solvate with as little as 0.02% acetone by weight is within the scope of the claims. ECF No. 59 at 7-8. Thus, according to Sanofi, the claims of the

'907 and '592 patents was also correctly stated in their Preliminary Proposed Claim Constructions, which were served on Sanofi on September 2, 2015.

'907 patent are so broad that they cover *any* solvate (not just acetone solvates) so long as there is a trace impurity of acetone. This is not what the inventors claimed or disclosed.

(1) The Intrinsic Record Only Discloses an Acetone Solvate With Between 5% and 8% Acetone, and Does Not Disclose "Channel Solvates."

Nowhere in the patent claims, specification, or prosecution history of the '907 patent is the term "channel solvate," or any similar term, used to describe the invention of the '907 patent. Sanofi does not identify any intrinsic evidence to support its contention and relies only on the unsupported assertion of its expert Dr. Atwood that "[a] POSA reading the patent specification would understand that the term 'acetone solvate' refers to a channel solvate that can exhibit both stoichiometric as well as non-stoichiometric behavior," and that "[n]on-stoichiometric solvates usually have channels or networks through which the solvent molecules are capable of diffusion." ECF No. 59-8 at ¶¶ 44, 25. However, Dr. Atwood provides no basis for concluding that the acetone solvate of cabazitaxel described by the patent is present in non-stoichiometric ratios, or for his assertion that a POSA would understand that the Drying Study results in a non-stoichiometric acetone "channel" solvate. Chyall Resp. Decl. at ¶¶ 6-9.[3] There is no such disclosure in the patent, which only indicates that drying at temperatures above 70 °C results in degradation of the solvate. The patent provides no spectroscopic data to characterize any product other than a solvate with 7.2% acetone. *Id.* at ¶ 9. Without such data, Dr. Atwood's assumption that a POSA would understand that the claimed acetone solvate is a "channel solvate," despite the patent making no such disclosure, is the only "support" Sanofi has for claiming products with as little as 0.02% acetone by weight.[4]

[3] "Chyall Resp. Decl." means the Responsive Declaration of Leonard J. Chyall, Ph.D., submitted concurrently herewith.

[4] [redacted] *See* ECF No.

Indeed, the specification of the '907 patent discloses that the claimed acetone solvate has a stoichiometric or near-stoichiometric amount of acetone. First, the Summary of the Invention of the '907 patent states that "[i]t has been found that the acetone solvate of [cabazitaxel] is *fully characterized* from a chemical viewpoint." ECF No. 58-7, '907 patent, col. 1, ll. 36-41 (emphasis added). Second, the patent discloses a single example of an acetone solvate of cabazitaxel—form A—including 7.2% acetone by weight. *Id.* at col. 2, l. 49-col. 3, l. 3. The patent notes that 6.5% acetone by weight would be the theoretical stoichiometric ratio. *Id.* at col. 3, l. 3. A POSA would understand that form A, which includes 7.2% acetone, corresponds to a near-stoichiometric ratio. *See* Chyall Resp. Decl. at ¶ 8. Third, the patent "fully characterizes" the disclosed acetone solvate of cabazitaxel by disclosing both a PXRD pattern and ^{1}H NMR data *only* for "the solvate form comprising acetone (*form A*) of the product of Example 1." ECF No. 58-7, '907 patent, col. 3, ll. 20-59 (emphasis added), Fig. 1; *see* Chyall Resp. Decl. at 7, 13-18. There is no data characterizing the compound resulting from the Drying Study.

The disclosure of the '592 patent provides further support for the claimed solvate only containing between 5% and 8% of acetone by weight. Although Sanofi argues that the '592 patent is extrinsic evidence to the '907 patent, it agrees that the term "acetone solvate" "necessarily means the same thing" in both patents and it acknowledges that the '592 patent expressly states that the acetone solvate used therein is the same as that disclosed in the '907 patent. ECF No. 59 at 10. The '592 patent, therefore, strongly informs the meaning of the claimed "acetone solvate" and it expressly states that the acetone solvate of cabazitaxel "may . . .

59-8 at ¶ 54. Sanofi concedes that a POSA would not have had access to, and thus would not have considered, this document when determining the scope of the claims of the patents-in-suit; this Court should disregard the polymorphism study for this reason. In any event, Sanofi's polymorphism study contradicts Dr. Atwood's opinions. *Infra* at 6.

contain[] between 5% and 8% . . . of acetone." ECF No. 58-8, '592 patent, col. 4, l. 47-col. 5, l. 11; ECF No. 58 at 7.

(2) The Drying Study Does Not Disclose an Acetone Solvate of Cabazitaxel with as Little as 0.02% Acetone by Weight.

Sanofi asserts, without support, that the products of the Drying Study with residual amounts of acetone (down to 0.02% by weight) "will exhibit the same PXRD fingerprint, and thus are considered the same acetone solvate crystalline form" as form A. ECF No. 59 at 8. The '907 patent, however, does not refer to the products of the Drying Study as examples of cabazitaxel acetone solvates. In fact, the '907 patent warns *against* following the excessive drying identified in the Drying Study. ECF No. 58-7, '907 patent, col. 2, ll. 31-42.

As explained in Defendants' opening brief, a POSA would understand that the product could be dried at between 30 and 60 °C, but that at higher temperatures, the solvated product was not being *dried*, but was being *destroyed*. ECF No. 58 at 8-9; ECF No. 58-1 at ¶ 37. Heating form A at excessive temperatures (greater than 70 °C) resulted in the formation of a completely different crystalline form, *i.e.*, an anhydrous form of cabazitaxel. ECF No. 58 at 9. Indeed, Sanofi filed another set of patent applications disclosing and claiming other forms of cabazitaxel, including an "anhydrous form B." *See id.* The Drying Study thus does not represent other "acetone solvates" with lower amounts of acetone.

Nonetheless Dr. Atwood argues, without support, that the claimed acetone solvate is a "channel solvate," and that a POSA reading the specification of the '907 patent would somehow know that even if a sample was excessively dried to remove virtually all of the acetone, the physical crystal structure would not change. ECF No. 59-8 at ¶¶ 46-47. As discussed above, there is no support in the patent for Dr. Atwood's conclusion that the cabazitaxel acetone solvate described in the '907 and '592 patents is a channel solvate. A POSA would understand that *any*

solvate, channel or not, that was exposed to heat, could lose some of its solvent constituents when excessively heated under vacuum. Chyall Resp. Decl. at ¶ 7. Without characterization data for the byproducts described in the Drying Study, there is no way to confirm Dr. Atwood's assertion that these byproducts would exhibit similar spectroscopic data to "form A," and thus no way to confirm Dr. Atwood's "channel solvate" theory. *Id.*

Furthermore, Dr. Atwood concludes, again based on the unsupported assumption that the cabazitaxel acetone solvate described in the '907 patent is a "channel solvate," that desolvating by heating would necessarily result in the retention of the same physical crystal structure, which he terms an "isomorphic desolvate." ECF No. 59-8 at ¶¶ 49-50. As discussed above, that conclusion is contradicted by express statements made in Sanofi's other filings with the U.S. Patent Office. *Supra* at 5. [redacted] ECF No. 59-8 at Ex. J, SA_JEV_0072337 (emphasis added); *id*. at ¶ 54; Chyall Resp. Decl. at ¶ 9. [redacted]

This alone is fatal to Dr. Atwood's claim that the residual acetone content of 0.02% from the Drying Study is isomorphic with form A.[5]

(3) Sanofi's Claim Differentiation Argument is Misplaced.

Sanofi argues that the only difference between claims 1 and 2 of the '907 patent is the addition of the words "comprising from about 5 to about 7 percent by weight of acetone" in claim 2, and that claim 2 is thus directed to the stoichiometric solvent amount, while claim 1 is

[5] Sanofi's proposed construction is also incorrect because its proposed upper limit of 7.2% by weight acetone is inconsistent with the full range of acetone described in the '592 patent specification and claim 4 of the '592 patent. ECF No. 58 at 11.

broader, and can contain stoichiometric and non-stoichiometric amounts of acetone. ECF No. 59 at 9. Under Defendants' construction of "acetone solvate," claim 2 would be narrower than claim 1 (*i.e.*, claim 1 would cover acetone solvates containing between 5% and 8% acetone by weight, and claim 2 would cover acetone solvates containing from about 5% to about 7% acetone by weight), and therefore, Defendants' construction does not violate the doctrine of claim differentiation.[6]

2. Figure 1 of the '907 Patent Should Not Be Incorporated Into the Construction.

Sanofi argues that an "acetone solvate" in the context of the '907 and '592 patents should exhibit a PXRD pattern that is "consistent with that of Figure 1 of the '907 patent." The Court should reject this improper attempt to read in a limitation from the specification. *See, e.g.*, *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330-31 (Fed. Cir. 2012); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324–27 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). The asserted patent claims do not include PXRD data or peaks, and do not mention Figure 1. Sanofi cannot import the limitation of Figure 1 where the claims are silent.

Furthermore, Sanofi's construction should be rejected because it creates uncertainty in the interpretation of the claims. *See Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003) (refusing to adopt a construction whose scope was not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes). Sanofi does not explain what it means to be "consistent with" a PXRD pattern. Sanofi states only that PXRD patterns represent "fingerprints characterizing particular crystal forms" and that the claimed acetone solvate would need to be "consistent with" that fingerprint.

[6] The parties are in agreement that the construction of "acetone solvate" for dependent claim 2 is the same as that for claim 1 with the clarification that claim 2 contains a further limitation as to the acetone content of the solvate ("from about 5 to about 7 percent by weight of acetone"). ECF No. 51-1 at C-1 n. 9.

ECF No. 59 at 7. PXRD patterns, like fingerprints, are unique. A match is obtained only by comparing *all* the peaks in one pattern to *all* the peaks in another pattern. *See* Chyall Resp. Decl. at ¶ 10-12. A POSA would not ascribe any meaning to the concept of being "consistent with" a PXRD pattern. *Id.* In an apparent attempt to clarify Sanofi's position, Dr. Atwood states that a POSA would understand that an "acetone solvate" would have a PXRD pattern that exhibited "at least the major peak positions depicted in FIG. 1." *See* ECF No. 59-8 at ¶ 43. He gives no guidance, however, as to how to determine what constitutes a "major peak position," or whether anything else is required to be "consistent with" a PXRD pattern. *Id.* Indeed, a POSA would recognize that a PXRD pattern exhibiting the "major" peaks of Figure 1 and other additional peaks not in Figure 1 could represent a completely different crystalline form. *See* Chyall Resp. Decl. at ¶ 12.

In focusing on the PXRD pattern, Sanofi ignores the ^{1}H NMR data provided in the patent specification. ECF No. 59 at 6. Sanofi gives no explanation for this inconsistency. Both the PXRD pattern and the ^{1}H NMR data set forth in the patent are described as being characteristic of "the product of example 1," that is, form A. ECF No. 58-7, '907 patent, col. 3, ll. 45-58. Sanofi provides no principled reason for its proposal to import Figure 1 into the claims, but not the ^{1}H NMR data that is part of the "full characterization" of form A described in the patent. The extrinsic evidence cited by Sanofi, Griesser, confirms that to fully characterize a solvate "combinations of several methods" are advantageous. ECF No. 59-1 at Ex. H (CabRef004976). Most likely, Sanofi ignores the ^{1}H NMR data present in the '907 patent because it is *inconsistent* with Sanofi's proposed construction. Chyall Resp. Decl. at ¶¶ 13-18. ^{1}H NMR is a technique that is useful for determining relative amounts of molecules in a sample. *Id.* at ¶ 14. A POSA would understand that the ^{1}H NMR data provided in the patent can only correspond to a solution

that has approximately equal parts cabazitaxel and acetone. *Id.* at ¶ 17. The ^{1}H NMR data disclosed in the patent does not support Sanofi's contention that the inventors were in possession of an acetone solvate with as little as 0.02% acetone by weight.

B. The Disputed Portions of the Preambles of '592 Patent Claims 1 and 27 Are Not Limiting.

In their Opening Brief, Defendants explained that certain portions of the preambles from claims 1 and 27 of the '592 patent are limiting, but that other portions are not limiting. In particular, for claim 1, Defendants explained that the phrase "a patient with prostate cancer that has progressed during or after treatment with docetaxel" from the claim 1 preamble is limiting because it provides antecedent basis for the term "said patient" appearing in the body of claim 1 and because it was added to the claim to distinguish the prior art, but that the phrase "[a] method for treating" from the claim 1 preamble is not limiting because it merely states a purpose or intended use of the claimed subject matter, rather than stating any required steps. ECF No. 58 at 13-18. Similarly, Defendants explained that the phrase "a patient with a castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel" from the claim 27 preamble is limiting because it provides antecedent basis for the term "the patient" appearing in the body of claim 27 and because it was added to the claim to distinguish the prior art, but that the phrase "[a] method of increasing the survival of" from the claim 27 preamble is not limiting because it merely states a purpose or intended use of the claimed subject matter, rather than stating any required steps. ECF No. 58 at 21-22.

Sanofi argues that the disputed portions of the preambles of claims 1 and 27 are limiting for a variety of reasons. As set forth below, none of these reasons has merit.

1. The Disputed Portions of the Preambles Do Not Provide Antecedent Basis for Other Limitations.

First, Sanofi argues that a portion of the preamble of claim 1 provides an antecedent basis for the term "said patient" found in the body of claim 1 and "the prostate cancer," found in dependent claims 2, 17, 20 and 24, and that a portion of the preamble of claim 27 provides an antecedent basis for the term "the patient" found in the body of claim 27. ECF No. 59 at 11. However, the portions of the preambles that provide the antecedent basis for these terms—"a patient with prostate cancer that has progressed during or after treatment with docetaxel" from the claim 1 preamble, and "a patient with a castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel" from the claim 27 preamble—are the portions that Defendants agree are limiting for the same reason given by Sanofi. ECF No. 58 at 16, 22. Notably, Sanofi does not argue that the disputed portion of either preamble provides antecedent basis for any terms appearing elsewhere in the claims.[7]

2. The Purpose of the Invention Should Not Be Read From the Specification into the Claims.

Second, Sanofi incorrectly argues that the specification indicates that a purpose of the invention is to treat prostate cancer, and that the purpose should be read into the claims. ECF No. 59 at 12. Just because a purpose of the invention is to treat prostate cancer does not mean that treating prostate cancer is a limitation of the claims. Indeed, one of the classic situations where a preamble is not limiting is where it merely states a purpose of the claimed subject matter, as numerous cases cited by Defendants in their opening brief hold. *See, e.g., Bristol-*

[7] For the same reason, Sanofi is wrong when it asserts that Defendants have agreed that the preambles of claims 1 and 27 are limiting by agreeing with Sanofi on a construction of a phrase that appears in both preambles ("prostate cancer that has progressed during or after treatment with docetaxel"). ECF No. 59 at 11. The phrase from the preambles for which Defendants agreed on a proposed construction comes from the portion of the preamble that Defendants have agreed is limiting, not from this disputed portion.

Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375 (Fed. Cir. 2001) ("*Bristol-Myers II*"). In *Bristol-Myers II*, the specification also stated the purpose recited in the preamble, but that was not sufficient to transform the statement of purpose in the preamble into a claim limitation.

3. The Doctrine of Claim Differentiation Does Not Help Sanofi.

Third, relying on the doctrine of claim differentiation, Sanofi argues that, if the disputed portions of the preambles of claims 1 and 27 are not limiting, then claims 24 and 28 would have the same scope, and thus the disputed portions should be interpreted to be limiting. ECF No. 59 at 13. Even assuming, *arguendo*, that claims 24 and 28 would have the same scope, that would not justify interpreting the disputed portions to be limiting. The doctrine of claim differentiation "is a guide, not a rigid rule." *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991) (quoting *Autogiro Co. of America v. U.S.*, 384 F.2d 391, 404 (Ct. Cl. 1987)). Claim differentiation "cannot broaden claims beyond their correct scope. . . Claims that are written in different words may ultimately cover substantially the same subject matter." *Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005) (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998)). Here, the disputed portions of the preambles are unambiguous statements of purpose and thus are not limiting. The "guide" of claim differentiation should not be allowed to override this principle. *See Bristol-Myers II*, 246 F.3d at 1376 (rejecting argument that a preamble that merely stated purpose of claimed subject matter should be construed as limiting because otherwise two claims would have same scope, stating "We decline to blindly apply the doctrine [of claim differentiation] in this case to supplant other canons of claim construction that compel our conclusion that independent claims 1 and 5 have identical scope. . . .").

4. During Prosecution, There Was No "Clear Reliance" on the Disputed Portions of the Preambles to Overcome a Rejection.

Finally, Sanofi incorrectly argues that the preambles were relied on during prosecution to distinguish prior art, and that they are limiting for that reason. ECF No. 59 at 13-15.

For statements in the prosecution history to be relevant, one must show "clear reliance" on the preamble to distinguish the prior art during prosecution. *See Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). The statements relied on by Sanofi are at best ambiguous. Notably, the case law relied on by Sanofi in support of this argument involved prosecution histories where the applicant stated that the preamble was a claim limitation. *See, e.g.*, *Rotatable Tech. LLC v. Motorola Mobility LLC,* 567 F. App'x 941, 943 (Fed. Cir. 2014); *Helsinn Healthcare SA v. Dr. Reddy's Labs., Ltd.*, No. 11-3962, 2015 WL 1817109, at *4, *8-*9 (D.N.J. Apr. 22, 2015) (during interview, applicants "highlighted the limitations that were in the claims, including… [reducing] cancer chemotherapy-induced nausea and vomiting," when the issue was whether preamble phrase "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" was limiting). In contrast, Sanofi does not point to a single statement where either applicants or the Examiner stated that the claims require "a method for treating" or "a method of increasing the survival."

Moreover, Sanofi does not argue that the disputed portions of the preambles were added to overcome a rejection of the claims. Indeed, Sanofi cannot make this argument because the disputed portion of each preamble was in the claim from the very beginning of prosecution. Original claim 1 in the application leading to the '592 patent (which became issued claim 1) required "A method for treating prostate cancer in a patient," and original claim 24 (which became issued claim 27) required "A method of increasing the survival of a patient." ECF No. 59-2 at SA_JEV_0001541-43. Indeed, as Defendants explained in their Opening Brief, the

portion of the preamble that was added to overcome a rejection was the portion requiring "a patient with prostate cancer that has progressed during or after treatment with docetaxel," which Defendants agree is limiting. In contrast, in *Helsinn*, relied on by Sanofi, the preamble language found to be limiting was added to overcome an enablement rejection. *See* 2015 WL 1817109, at *8-*9.

Moreover, the statements from the prosecution history relied upon by Sanofi are referring to "unexpected results"[8] that applicants alleged were produced when the claimed method was carried out (*i.e.*, when cabazitaxel and a corticoid were administered to a prostate cancer patient), rather than to what the claims actually require. For example, the statement from the Examiner's Reasons for Allowance relied on by Sanofi (ECF No. 59 at 14 (citing ECF No. 59-2 at SA_JEV_0004765-66)) that "it is surprising and unexpected that the claimed combination of cabazitaxel and a corticoid are clinically effective in the treatment of prostate cancer that has progressed during or after treatment with docetaxel" does not indicate that "clinical effectiveness" or "treatment of prostate cancer" is a claim limitation. Rather, the Examiner was accepting applicants' proffered evidence that the claimed method (*i.e.*, carrying out the steps required by the body of the claim) was patentable because, in the Examiner's view, it allegedly showed "unexpected results"—namely, clinical effectiveness in the treatment of prostate cancer that has progressed during or after treatment with docetaxel.[9] However, that does

[8] One way that an applicant can establish that a patent claim is not obvious is by showing that the claimed subject matter may produce unexpected results in comparison to the closest prior art. *See Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014).

[9] Applicants did not compare the claimed subject matter to the closest prior art (the numerous prior art references describing the TROPIC study) or even disclose that prior art to the Examiner, and thus the Examiner's acceptance of applicants' proffered evidence of unexpected results is not probative of non-obviousness of the claims.

not mean that a purportedly "unexpected result" should be converted into an element required by the claims.[10]

Indeed, Sanofi's argument contradicts Federal Circuit law which mandates that while an "unexpected result" is a benefit that may sometimes result from carrying out claimed subject matter, that does not render the "unexpected result" a required element of the claims. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) (*en banc*). In *Purdue Pharma*, the district court interpreted the asserted claims to require the result of "acceptable pain control for 90% of patients over a four-fold dosage range" based on applicants' argument during prosecution that the claimed subject matter produced this unexpected result. *Id.* at 1135. The Federal Circuit reversed this claim interpretation, holding that the claims did not require this unexpected result. *Id.* at 1136 (finding that "property of, or a result of administering" did not function as claim limitation).

Likewise, in *McNeil-PPC, Inc. v. Perrigo Co.*, 443 F. Supp.2d 492, 505 (S.D.N.Y. 2006), the court refused to import into the claims an unexpected result that applicants relied upon during prosecution, stating:

> It is true that a patent applicant using unexpected results to show non-obviousness must provide data commensurate in scope with the claims which the evidence is offered to support. However, that does not mean that courts mechanically import limitations from the test results into the claims....Moreover, the Federal Circuit has held that claims allowed based on "surprising results" may be construed more broadly that the results themselves. ...
> The submission of extraordinary results that are narrower in scope than the claims does not, by itself, impose a limitation on the construction of the claims.

Id. (internal citations omitted).

[10] The only subject matter that the Examiner explicitly indicated is required by the claims is a "combination of cabazitaxel and a corticoid," which the Examiner did by referring to "the claimed combination of cabazitaxel and a corticoid." The Examiner did not refer to being "clinically effective" or the "treatment of prostate cancer" as "claimed" elements.

Similarly, this Court rejected an argument that "unexpected results" relied upon during prosecution mandated that a preamble reciting that result functions as a claim limitation because the preamble was merely a statement of intended use. *Bristol-Myers Squibb Co. v. Immunex Corp.*, 86 F. Supp. 2d 447, 451 n. 4 (D.N.J. 2000) ("*Bristol-Myers I*"), *aff'd-in-part, vacated-in-part, and remanded*, 246 F.3d 1368 (Fed. Cir. 2001).

Here, to convince the Examiner to allow the claims, Sanofi pointed to the alleged unexpected result shown in the Sartor Declaration that the claimed subject matter (*i.e.*, the claimed combination of cabazitaxel and a corticoid) was clinically effective in the treatment of prostate cancer that has progressed during or after treatment with cabazitaxel. ECF No. 59-2 at SA_JEV_0004403 ("Dr. Sartor further demonstrates that the results of the claimed invention were truly unexpected to those skilled in the art."). The Examiner accepted that argument in allowing the claims. *Id*. at SA_JEV_0004765. But, just as in *Purdue, McNeil* and *Bristol-Myers I*, that did not transform the alleged unexpected result (of being clinically effective in the treatment of prostate cancer that has progressed during or after treatment with cabazitaxel) into a claim limitation.

At the very least, it is ambiguous whether Sanofi or the Examiner considered "clinical effectiveness" to be a required element of the claims, or simply an unexpected (and unclaimed) result that the claimed subject matter may produce. This does not constitute the sort of "clear reliance" on the preamble to overcome a rejection that is required to convert preambles into claim limitations. *See Catalina*, 289 F.3d at 808. Accordingly, Sanofi's argument that the prosecution history warrants converting the disputed portions of the preambles into claim limitations should be rejected.

C. If "A Method for Treating" Is Limiting, It Requires Only an Attempt to Produce a Therapeutic Effect, Not Successful Treatment.

If the disputed portion of the claim 1 preamble is held to be limiting, then "treating" should be construed to mean "attempting to produce a therapeutic effect" for several reasons, including (a) that the claims require administering cabazitaxel and a corticoid to patients previously and unsuccessfully "treated" with docetaxel, which implies that treating a patient does not require success, and (b) the specification repeatedly describes instances of patients being "treated" where no therapeutic effect was produced. ECF No. 58 at 18-20. Sanofi's argument that "treating" should be interpreted to require actually producing a therapeutic effect (*i.e.*, successfully treating a patient) should be rejected.

First, Sanofi argues that the claims at one point required an "effective amount" of cabazitaxel, and that "effective amount" is defined in the specification as an amount "that produces an effect on the cancer to be treated." ECF No. 59 at 15-16. But Sanofi deleted the phrase "effective amount" from all of the claims during prosecution, and thus even if that phrase imported some sort of efficacy requirement, it could not import such a requirement into the issued claims of the '592 patent because they do not require an "effective amount" of cabazitaxel.

Even if the court accepts Sanofi's unreasonable proposition that the phrase "effective amount" be read into claim 1, Sanofi's own clinical data shows that the phrase "effective amount" neither means nor requires efficacy. Sanofi asserts that the "20-25 mg/m^2 cabazitaxel dose range of Claim 1 was considered by the applicants to be an 'effective amount' of cabazitaxel," ECF No. 59 at 16, yet only 14.4% of the 378 patients treated in a phase 3 clinical trial had a tumor response after being treated with 25 mg/m^2 cabazitaxel. ECF No. 58-8, '592

patent, col. 11, ll. 45-66. Accordingly, the specification teaches that an "effective amount" is still no more than an attempt to produce a therapeutic effect.

Second, Sanofi argues that the specification indicates that therapeutic effectiveness is a "fundamental feature" of the alleged invention, and that this feature should thus be read into every claim. ECF No. 59 at 16-17. However, the results of the clinical study described in the specification show that no response (*i.e.*, no therapeutic effect) was observed in the majority of the patients who were administered cabazitaxel and a corticoid with the exact doses set forth in claim 1, even though all patients were referred to as having been treated. ECF No. 58 at 19; ECF No. 58-8, '592 patent, col. 11, ll. 45-66; ECF No. 58-3 at ¶ 19; Schiff Resp. Decl. ¶¶ 5-10[11]. Sanofi is essentially asking the Court to read a limitation (producing a therapeutic effect) from the specification into the claims, which is strongly disfavored.

Third, Sanofi points to several instances in the prosecution history where applicants argued that the claims should be allowed because it was unexpected that prostate cancer could be "successfully treated" with the combination of cabazitaxel and a corticoid. ECF No. 59 at 17-18. However, these instances demonstrate just the opposite of what Sanofi is arguing. Specifically, the use of the phrase "successfully treat" in the prosecution history shows that the word "treat" by itself does not require success. Otherwise, the adverb "successfully" in the phrase "successfully treat" would be superfluous. Because claim 1 recites "[a] method for treating," and not "a method for successfully treating," it is clear that claim 1 does not require successful treatment. Rather, claim 1 requires only an attempt to produce a therapeutic effect, just as Defendants have argued.

[11] "Schiff Resp. Decl." means the Responsive Declaration of Jonathan D. Schiff, M.D., submitted concurrently herewith.

For all of these reasons, Sanofi's arguments should be rejected, and if the disputed portion of the claim 1 preamble is held to be limiting, then "treating" should be interpreted as attempting to produce a therapeutic effect.

D. If "A Method for Increasing the Survival of a Patient" Limits Claim 27, It Is Indefinite.

If the disputed portion of the claim 27 preamble is held to be limiting, then the phrase "A method of increasing the survival of a patient" is indefinite because: (1) it is not possible to determine whether the survival of any one patient ("a patient") is increased because one cannot compare the effect of the claimed cabazitaxel regimen in one patient with the effect of a different regimen in the same patient—one cannot administer two regimens at the same time to the same patient and compare the effects; and (2) it is not clear what the claimed cabazitaxel regimen should be compared against, and different results would be produced depending on what regimen was used as the comparator. ECF No. 58 at 22-24. Sanofi makes several arguments for why the claim 27 preamble is not indefinite, each of which should be dismissed.

First, Sanofi attempts to rewrite the plain language of claim 27 to require a statistically significant increase in overall survival in a population of patients, instead of simply requiring an increase in survival of "a patient." ECF No. 59 at 20-22. Sanofi is careful to avoid using the phrase "a population of patients" in its proposed construction of the claim 27 preamble (because it is totally inconsistent with the claim's use of the phrase "a patient"), but it is clear that Sanofi's proposed construction requires an increase in a population of patients because "a statistically significant increase" (which is part of Sanofi's proposed construction) can only be shown with reference to a patient population (*i.e.*, there is no such thing as a "statistically significant increase" in the survival of a single patient). Schiff Resp. Decl. ¶¶ 13-15. Such a re-drafting of the claim should not be permitted.

Second, Sanofi argues that the claimed cabazitaxel regimen should be compared to "no treatment or purely palliative treatment" in determining whether survival is increased. However, by definition, claim 27 requires the patients that receive the claimed cabazitaxel regimen to have previously been treated with docetaxel. Thus, one of ordinary skill would have considered one reasonable comparator regimen to be docetaxel treatment. ECF No. 58-3 at ¶ 35. Sanofi does not explain why this would not be a possible comparator regimen, and its expert Dr. Petrylak implies that this would be a reasonable comparator. Schiff Resp. Decl. ¶¶ 17-18. Moreover, Sanofi implies that the same results would be observed in patients who received no treatment and patients who received purely palliative treatment; otherwise, the claim would be indefinite because the claimed cabazitaxel regimen could potentially increase the survival of a patient versus one regimen, but not the other. However, Sanofi does not explain why the same results would be expected when patients were given no treatment and when patients were given purely palliative treatment. A person of ordinary skill in the art would not expect the results to be the same from these two regimens for various reasons, including that the results from "merely palliative treatment" would likely benefit from the well-known placebo effect, while such would not be the case with no treatment. ECF No. 58-3 at ¶ 35; Schiff Resp. Decl. ¶ 16.

Third, Sanofi argues that the claim 27 preamble is not indefinite because Defendants' argument that it is impossible to determine whether survival was increased in a given patient relates to proving infringement and not to whether the claim is indefinite. However, Sanofi cites only pre-*Nautilus* cases, which are of limited relevance given that *Nautilus* significantly relaxed the standard for proving indefiniteness. In contrast, Defendants cited two post-*Nautilus* cases in their opening brief where claims were held indefinite because they required a determination that was impossible to make. ECF No. 58 at 23-24. In any event, this is not a case where the scope

of the claim is clear but there is no known method of determining whether that clear scope is satisfied. Instead, here the parties differ over several aspects of what the claim requires, including (a) whether it requires an increase in survival in a single patient or across a population of patients, and (b) the regimen against which the claimed cabazitaxel regimen should be compared.

For all of these reasons, if the disputed portion of the preamble is held to be limiting, Sanofi's arguments should be rejected, and the preamble of claim 27 should be held to be indefinite.

E. Sanofi's Proposed Construction of "Administering" Finds No Support in the '592 Patent Specification or Prosecution History.

"Administering" should be construed as "delivering into the body of the patient" because the plain language of '592 patent claims 1 and 27 define administration as delivering cabazitaxel directly to the patient, and because "administration" is used consistently in that manner throughout the '592 patent and its prosecution history. ECF No. 58 at 24-27. Sanofi's construction of "administering"—"prescribing, supervising, or managing the formal taking of" is not supported by the claim language and erroneously assumes that the party carrying out the "treating" and "administering" steps of the claimed methods must be a physician. ECF No. 59 at 24-25. As explained below, the '592 patent imposes no such requirement, and therefore there is no justification for Sanofi's overly broad construction of "administering" to reach conduct such as "prescribing," "supervising," and "managing" that have nothing to do with "administering," as used in the '592 patent. Sanofi's construction relies almost exclusively on extrinsic evidence—in the form of unsupported assertions from its expert declarant, Dr. Petrylak, and inapposite general dictionary definitions—that should be rejected by this Court. Finally, Sanofi's overly

broad construction would cover methods that do not result in treatment of any kind, and Sanofi's construction should be rejected for that additional reason.

1. The Claim Language Does Not Support Sanofi's Construction.

Sanofi argues that the claim language is inconsistent with Defendants' construction because claims 1 and 27 "comprise a single step of administering cabazitaxel in combination with a corticoid" and only recite "administering" once, whereas Defendants' construction requires "two administering steps by two different individuals because prednisone is an oral medication and cabazitaxel is given intravenously." ECF No. 59 at 24. Although the term "administering" appears once in the claims, there is no claim language limiting "administering" to a single act. Instead, the claims expressly require "administering" two different medicaments. Indeed, the specification makes it clear that the cabazitaxel and the corticoid are administered via separate acts, stating that the recommended regimen is for the cabazitaxel to be administered by intravenous infusion every three weeks, while the corticoid is administered orally every day. ECF No. 58-8, '592 patent, col 3, 11. 2-21, col. 5, 11. 39-54, claims 5, 14, 19, 23, 25 and 29. Moreover, under Sanofi's reasoning, its own construction is inconsistent with the claim language because it also requires multiple acts including at least: (1) prescribing cabazitaxel and/or a corticoid; (2) filling the prescription/s; (3) administering cabazitaxel; and (4) administering a corticoid. Therefore, Sanofi's arguments that the claim language is inconsistent with Defendants' construction should be rejected.

2. The Claims Are Not Limited to Physicians Who "Treat[]" and "Administer[]."

The words "supervising" and "managing" are found nowhere in the '592 patent. "Prescribing" is used in the '592 patent specification only in connection with educational materials such as "prescribing information" (ECF No. 58-8,'592 patent, col. 9, ll. 20-28), but not

in any way in connection with "administering."[12] Sanofi's only justification for its overly broad construction of "administering" is its restrictive reading of '592 patent claims 1 and 27 as limited to methods carried out by physicians only. That is, Sanofi's construction of "administering" erroneously assumes that the party carrying out the "treating" and "administering" steps of the claimed methods must be a physician. ECF No. 59 at 24-25. Specifically, Sanofi argues, without any intrinsic support, that "[a] POSA would understand that the claims are directed to treating physicians because the claims are methods for treating patients that have progressed after docetaxel therapy." *Id*. at 24.

But the '592 patent does not restrict the claimed methods to practicing physicians—***any person*** "administering," *i.e.*, "delivering into the body of the patient," "20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, in combination with a corticoid," is, by the very definition set forth in claim 1, "treating."[13] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention"). That is, the '592 patent does not exclude a physician's assistant or nurse who infuses a patient with 20 to 25 mg/m^2 of cabazitaxel and who provides the patient with the corticoid from the claimed methods. There is nothing in the '592 patent that excludes a

[12] This is in contrast to the facts in *Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, No. 9:07-CV-46, 2008 WL 2359961 (E.D. Tex. June 5, 2008), relied upon by Sanofi. ECF No. 59 at 25. In *Iovate*, the patent owner was able to point to numerous portions of the specification where "administering" was "used in the specification to denote an individual managing the administration of something to subjects." *Iovate*, 2008 WL 2359961, at *2. Sanofi can point to no such support here, and therefore, *Iovate* is inapposite. Sanofi's reliance on a claim construction order that contains no facts or analysis issued in *Accorda Therapeutics, Inc. v. Apotex, Inc.*, No. 08-4937 (GEB-MCA), ECF No. 85 (D.N.J. Jul. 2, 2010) should be rejected.

[13] This is consistent with Defendants' argument that the "method for treating" portion of the claim 1 preamble is not limiting because it merely recites an intended purpose and because the body of the claim recites a complete method by defining what "treating" is, *i.e.* "administering . . . a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, in combination with a corticoid." ECF No. 58-8, '592 patent at claim 1; *see also*, ECF No. 58 at 13-18.

patient who "self-infuses" with 20 to 25 mg/m^2 of cabazitaxel and who concomitantly takes a corticoid from the scope of claims 1 and 27. Thus, the entire premise of Sanofi's proposed construction is incorrect and the construction should be rejected.

3. Sanofi's Analysis Proceeds in a Backwards Fashion Prohibited by the Federal Circuit and Leads to an Erroneous Result.

Sanofi's analysis for "administering" proceeds first by relying on extrinsic evidence in the form of a declaration from its expert, Dr. Petrylak, to support its premise that the claims are limited to methods carried out by physicians, and then by crafting a definition for "administering" based on its premise that physicians must be doing the "administering." This is in conflict with how the Federal Circuit has mandated that claim construction proceed. In *Phillips*, the Federal Circuit made clear that claim construction starts first with an examination of the claims themselves, then proceeds to an examination of the specification, then the prosecution history, and then, last, extrinsic evidence. *Phillips*, 415 F.3d at 1312-19; *see also*, *Vitronics*, 90 F.3d at 1582 ("[I]n interpreting an asserted claim, the court should look first to the intrinsic evidence."); *Docusign, Inc. v. Sertifi, Inc.*, 468 F. Supp. 2d 1305, 1308 (W.D. Wash. 2006) ("Plaintiff's total reliance on the viewpoint of [its experts] demonstrates a misapprehension of the importance of *Phillips* and its progeny: the specification is where the inquiry begins (i.e., *not* the expert declaration).").

This Court should reject Sanofi's approach and instead begin its inquiry with a focus on the intrinsic record. The '592 patent and its prosecution history consistently reflect an understanding and intention on the part of the patentees that "administering" means directly "delivering into the body of the patient." ECF No. 58 at 25-27. The Court's inquiry should start and end there and Sanofi's extrinsic evidence should be rejected.

4. Sanofi's Extrinsic Evidence Should Be Rejected.

Sanofi relies almost exclusively on the declaration of its expert, Dr. Petrylak, to support its assertion that the claims are limited to methods carried out by physicians and that physicians can "administer[]" by simply "prescribing," "supervising," or "managing." ECF No. 59 at 24-25. Sanofi argues that its construction "takes into account the real-world practice of treating prostate cancer patients," and cites almost exclusively to the Petrylak declaration in support of this alleged "real-world practice." *Id*.

Dr. Petrylak's declaration, in turn, asserts that "a POSA would understand that it is a physician who ***selects and decides to administer*** cabazitaxel in combination with a corticoid to treat their patients." ECF No. 59-5 at ¶ 70 (emphasis added). But "select[ing] and decid[ing] to administer" is not "administering" as the term is used in the '592 patent, as evidenced by the plain language of claims 1 and 27, which specify "administering ***to said patient***" a dose of cabazitaxel in combination with a corticoid (Schiff Resp. Decl. ¶ 23), and as evidenced by the rest of the intrinsic record as explained in Defendants' Opening Brief (ECF No. 58 at 24-27). "[S]elect[ing] and decid[ing] to administer" is another way of saying "prescribing," which the '592 patent nowhere correlates with "administering." "[A] court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history." *Phillips*, 415 F.3d at 1318 (internal quotations and citations omitted). This Court should discount Dr. Petrylak's attempt to conflate "administering" with "prescribing," an activity that is outside the scope of the claimed methods and nowhere discussed in the '592 patent.

Dr. Petrylak next asserts that "language from the specification indicates to a POSA that the claims are directed to the treating physician." ECF No. 59-5 at ¶ 71. But Dr. Petrylak does not provide any support for this assertion, whether by citation to the '592 patent or to the prior

art literature. Although Dr. Petrylak acknowledges evidence Defendants have identified that shows that Sanofi has used "administering" in regulatory submissions in a manner consistent with Defendant's proposed construction ("delivering into the body of the patient"), without basis he dismisses Defendants' proposed construction and endorses Sanofi's overly broad construction.[14] ECF No. 59-5 at ¶ 79-80. "[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court," *Phillips*, 415 F.3d at 1318, and Dr. Petrylak's unsupported assertions should be rejected for that reason.

Sanofi also relies on a general dictionary definition for "administer" from Merriam-Webster's Collegiate Dictionary. ECF No. 59 at 26. As the Federal Circuit has pointed out:

> [G]eneral dictionaries collect the definitions of a term as used not only in a particular art field, but in many different settings . . . For that reason, we have stated that a general-usage dictionary cannot overcome art-specific evidence of the meaning of a claim term.

Phillips, 415 F.3d at 1321-22 (internal quotations and citations omitted). The general dictionary definition for "administer" that Sanofi relies on relates to areas unrelated to the cancer treatment context, such as "trust fund" administration and administering "punishment." See ECF No. 59-3 at SA_JEV0184063. The Court should disregard this general dictionary definition as inconsistent with how the '592 patent uses the term "administering."

The Concise Dictionary of Modern Medicine definition Sanofi relies upon (ECF No. 59 at 26) also does not support its construction. Sanofi's reliance on "by either a health practitioner or his authorized agent and under his direction" from this definition is misplaced as the definition nowhere suggests that the "health practitioner" who authorizes the "agent under his direction" is

[14] Dr. Petrylak also ignores the fact that the label for the Jevtana® drug product—which he attaches as an exhibit to his declaration—uses "administer" in a manner that is consistent with Defendants' proposed construction, but not consistent with Sanofi's proposed construction. Schiff Resp. Decl. ¶¶ 20-22 (for example, the Jevtana® label instructs one to use a certain type of filter "during administration").

"administering," *i.e.* "apply[ing] a substance . . . to the body of a [patient]." ECF No. 59-3 at CabRef0005047.

5. Interpreting "Administering" to Simply Mean "Prescribing" to a Patient May Not Actually Result in Treatment.

Finally, adopting Sanofi's construction would lead to the absurd result that carrying out the claimed method and "administering" may not lead to treatment, as it is generally understood that patients do not always comply with a "prescrib[ed]" treatment, or treatment "supervis[ed]" or "manag[ed]" by a physician. By contrast, adoption of Defendants' proposed construction would always result in treatment because when administered the medication is "delivered into the body of the patient."

F. "[Where/Wherein] the Cabazitaxel is in"[15] is Clear and Unambiguous and Needs No Further Construction.

1. Sanofi's Unsupported Construction Is an Attempt to Preserve a Factually and Legally Baseless Claim of Infringement.

As noted in Defendants' Opening Brief, the plain and ordinary meaning of "[where/wherein] the cabazitaxel is in" is clear and unambiguous and requires no further construction from the Court. ECF No. 58 at 27-30. Defendants Fresenius, Apotex, Breckenridge and Mylan's cabazitaxel products will be administered as a liquid solution, not as a solid. Because none of the cabazitaxel products will be administered as a solid, those Defendants cannot infringe '592 patent claims 3 or 6 if they are construed to have their plain and ordinary

[15] In their Opening Briefs, the parties have addressed "where the cabazitaxel is in the form of" of '592 patent claim 3 and "wherein the cabazitaxel is in base form" of '592 patent claim 6 separately (*see* ECF No. 58 at 27-30; ECF No. 59 at 27-29), but the disputed portion of both those terms is "[where/wherein] the cabazitaxel is in;" for brevity the Defendants focus on the disputed portion only. Sanofi argues that this disputed portion should be rewritten as "wherein the cabazitaxel active pharmaceutical ingredient [is/has]" (ECF No. 59 at 27-29); Defendants dispute this and maintain that the disputed portion should have its plain and ordinary meaning, *i.e.* that the cabazitaxel administered in claim 1 be in either solid crystalline acetone solvate form (claim 3) or base form (not in the form of a hydrate or solvate) (claim 6) (ECF No. 58 at 27-30).

meaning. Sanofi's attempt to substitute "active pharmaceutical ingredient" for "cabazitaxel" is an attempt to preserve an infringement contention that otherwise is untenable.[16] Even if Sanofi's erroneous construction is adopted, Defendants disagree that Sanofi's construction would allow it to prove infringement by simply establishing that Defendants' cabazitaxel products are formulated with cabazitaxel acetone solvate. ECF No. 58 at 29 n.13.

2. The Intrinsic Record Does Not Support Sanofi's Construction.

Sanofi's only argument in support of its construction appears to be that its construction must be adopted or else the claims do not make sense. Specifically, Sanofi argues that "[where/wherein] the cabazitaxel is in" recited in '592 patent claims 3 and 6 must refer to the pre-formulated "bulk" API or else the claims do not make sense as patients cannot be intravenously infused with solid crystals. ECF No. 59 at 27-29.

But Sanofi's argument is premised on an incorrect assumption: that the '592 patent claims are limited to intravenous administration. In support of this assumption, Sanofi states that "the specification only discusses parenteral, specifically intravenous, administration of cabazitaxel where the cabazitaxel is dissolved." ECF No. 59 at 27. However, the '592 patent claims are written to be formulation-independent—that is, they do not specify in what type of formulation (or composition) the cabazitaxel needs to be administered. ECF No. 58-8, '592 patent at claims 1-30. Further, while the '592 patent examples involve liquid injectable

[16] Sanofi cites *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008) which held that "a determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." This is not the case here. The word "cabazitaxel" does not have more than one ordinary meaning. Nor do the parties disagree about what the ordinary meaning of "cabazitaxel" is, as was the case in *O2 Micro*. Defendants simply argue that the term "cabazitaxel" should mean "cabazitaxel," and not "active pharmaceutical ingredient."

formulations of cabazitaxel, nothing in the specification excludes other formulations from the claimed methods.[17]

Sanofi has also asserted against Fresenius, Apotex, Breckenridge, Mylan and others the '170 patent, which claims cabazitaxel itself and compositions containing cabazitaxel (ECF No. 59 at 1), and which discloses that cabazitaxel may be formulated as "compositions [that] take the form of tablets, pills, powders or granules which can be administered orally." ECF No. 58-6, '170 patent, col. 27, ll. 7-9. Thus, the premise for Sanofi's erroneous construction—that the claimed methods are limited to administration of liquid compositions by intravenous infusion—is without support and contradicted by the evidence of record. It is without support because the plain language of the '592 patent claims do not limit the claimed methods to administration by liquid intravenous infusion,[18] and it is contradicted by the evidence of record because Sanofi's own patents disclose that cabazitaxel may be administered as a solid composition. Indeed, the '592 patent itself instructs that:

> Cabazitaxel ***may be administered*** in base form . . . ***or in the form of a hydrate. It may also be a solvate***, i.e. a molecular complex characterized by the incorporation of the crystallization solvent into the crystal of the molecule of the active principle . . . .

ECF No. 58-8, '592 patent, col. 4, ll. 40-45 (emphasis added). Thus, the '592 patent expressly includes administration of solid cabazitaxel acetone solvate crystals as within the claimed methods, and therefore does not limit the claims to liquid injectables or exclude administration of cabazitaxel as a solid dosage form. Had the '592 patentees intended to claim intravenous administration of a liquid that was made with cabazitaxel acetone solvate or the base form, as

[17] For example, the patent states that "*in some aspects* of the invention, cabazitaxel may be administered by intravenous infusion at a dose of between 15 and 25 mg/m^2." ECF No. 58-8, '592 patent, col. 3, ll. 16-18. This envisions alternative methods of administration, because it only refers to intravenous infusion as "some aspects" of the invention.

[18] Moreover, Sanofi has not sought a construction limiting the claimed methods to intravenous liquid infusion, and has thus waived this argument.

Sanofi erroneously maintains, they could and would have expressly said just that; instead they contemplated and intended that cabazitaxel could be administered a variety of different ways, including as a solid dosage form, and that is what they claimed.

When the '592 patent claims are correctly viewed as formulation-independent (*i.e.*, not limited to administration of a particular dosage form), the acetone solvate limitation of dependent claim 3 makes perfect sense in that it specifies administration of cabazitaxel as a dosage form that contains cabazitaxel acetone solvate crystals, such as a tablet. Sanofi's construction should therefore be rejected because the entire premise for its construction is incorrect and does not warrant a rewriting of the '592 patent claims.

3. Sanofi Is Attempting to Improperly Rewrite Claims 3 and 6.

Case law is clear that "[c]laims mean precisely what they say." *Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1355 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 648 (U.S. 2007). Sanofi cannot now "clarify" what it meant in an effort to ensnare Defendants' products, which are clearly outside the scope of the claims. Claim 1, from which claim 3 depends, is broad enough to include not only liquid formulations, but also solid formulations, including tablets, capsules, lozenges, etc. But claim 3 is narrower, and is only directed to the method of claim 1, "where the cabazitaxel is in the form of an acetone solvate," *i.e.*, where the cabazitaxel is administered as a solid that contains cabazitaxel acetone solvate crystals. Defendants will not be marketing solid cabazitaxel formulations, and thus do not infringe claim 3 when it is given its plain meaning. Sanofi cannot broaden the meaning of this claim beyond what is stated in the claim itself. *See General Elec. Co. v. ITC*, 685 F.3d 1034, 1037 (Fed. Cir. 2012) ("a possibly broader disclosure accompanied by an explicit narrow claim shows the inventor's selection of the narrow claim scope"); *see also Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1373–74 (Fed. Cir. 2004) (construing a claim consistent with the

claim language where the claim was directed to heating dough "to" a temperature of between 400 and 850 F, despite the examples stating that the dough should be baked "at" temperatures of 680-850 F).

4. Sanofi's Extrinsic Evidence Is Inapposite.

Sanofi points to extrinsic evidence in the form of Defendants' Joint Invalidity Contentions as support for its construction, asserting that Defendants "previously construed" Claim 3 as referring to the API. ECF No. 59 at 28. This quote is taken from contentions, not claim construction briefing. It is directed to an argument that claim 3 of the '592 patent is anticipated by Sanofi's publicly disclosed clinical trials. Defendants however, expressly state in those contentions that they were not taking a position on claim construction, because the claim construction process had not yet occurred. Supplemental Decl. of Roger J. Kiley, Esq. (submitted concurrently herewith) Ex. 1. Thus, the arguments contained in Defendants' invalidity contentions cannot be considered judicial admissions. *See Lam Research Corp. v. Schunk Semiconductor*, 65 F. Supp. 3d 863, 870-71 (N.D. Cal. 2014). As the *Lam* court found, statements concerning the scope or meaning of claims in patent invalidity contentions are not formal judicial admissions, they are "statements of law or legal argument," which fall outside of the concept of judicial admissions. *Id.* at 870. Even if such statements could be considered "judicial admissions," they are not binding on this Court, which has an independent obligation to construe the claims based on the intrinsic evidence in the first instance. *Id.* at 871-72.

III. CONCLUSION.

For the reasons discussed above and in Defendants' Opening Brief, Defendants respectfully request the Court to construe the disputed terms in accordance with their proposed constructions.

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